

K012788

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MAR 15 2002

Orthopaedic Division

Smith & Nephew, Inc.
1450 Brooks Rd., Memphis, TN 38116 U.S.A.
901-396-2121, For information: 1-800-821-5700
For orders and order inquiries: 1-800-238-7538

Smith+Nephew**510(k) Summary of Safety and Effectiveness**

Submitter's name: Smith & Nephew, Inc., Orthopaedic Division

Submitter's address: 1450 Brooks Road, Memphis, TN 38116

Submitter's telephone number: Direct phone: 901-399-6487 or FAX: 901-398-5146

Contact person: David Henley, Senior Clinical/Regulatory Affairs Specialist

Date summary prepared: March 15, 2002

Trade or proprietary device name: UHMWPE Components of the *Cofield²*, the *Neer II*, and the *Neer III Total Shoulder Systems* Sterilized with the VHP[®] Sterilization Process

Common or usual name: Cofield², Neer II, and Neer III Total Shoulder System UHMWPE Components

Classification name: 21 CFR 888.3660, shoulder joint metal/polymer, semi-constrained cemented prosthesis

**Substantially Equivalent Legally
Marketed Devices**

- Cofield² Total Shoulder System – Smith & Nephew, Inc.
- Neer II Total Shoulder System – Smith & Nephew, Inc.
- Neer III Total Shoulder System – Smith & Nephew, Inc.

Device Description

There have been no changes in indications for use, design, or material property changes to any Cofield², Neer II, or Neer III Total Shoulder System UHMWPE all polyethylene glenoid components that will be sterilized using the VHP[®] process.

The VHP[®] sterilization process uses hydrogen peroxide (H₂O₂) vapor for sterilization of Cofield², Neer II, and Neer III Total Shoulder System components (all polyethylene glenoids) manufactured from UHMWPE using the Century SL VHP[®] Sterilizer. Sterilization is achieved by a series of H₂O₂ gas injections at deep vacuum set points. Aeration of the medical devices after sterilization is conducted by a series of chamber evacuations.

Device Intended Use

The Cofield² Total Shoulder System, the Neer II Total Shoulder System, and the Neer III Total Shoulder System are indicated for use as orthopaedic implants for the partial or total replacement of the human shoulder joint articulating either directly against the glenoid face or a compatible glenoid component, respectively.

The Cofield² Total Shoulder System, the Neer II Total Shoulder System, and the Neer III Total Shoulder System are intended for the following:

Proximal Humeral Prosthesis – (1) complex, acute fractures or fracture-dislocations of the humeral head (e.g. trauma - three and four-part injuries in the Neer classification, or head splitting, or head impression fractures); (2) complex, chronic fractures or fracture-dislocations of the humeral head with malunion, nonunion of a small osteoporotic head fragment, or chronic dislocation with loss of humeral head cartilage, or large impression fractures; (3) avascular necrosis with intact glenoid cartilage; and (4) selected patients with arthritis who do not have adequate scapular bone to support a glenoid component or must engage in moderately heavy activities.

Total Shoulder Arthroplasty (when used in conjunction with a compatible glenoid component) – severe destruction of the glenohumeral articular surfaces with intractable chronic pain in rheumatoid arthritis, osteoarthritis, traumatic arthritis, cuff tear arthroplasty, ancient septic arthritis avascular necrosis with secondary glenoid changes, radiation necrosis, and other failed reconstructive procedures. The subject all poly glenoid components are intended for cemented fixation only and for single use only.

The Orthopaedic Division of Smith & Nephew, Inc. will utilize the VHP[®] sterilization process to terminally sterilize all orthopaedic implant components manufactured from UHMWPE material in the Cofield² Total Shoulder System, the Neer II Total Shoulder System, and the Neer III Total Shoulder System (all polyethylene glenoids).

Technological Characteristics

The VHP[®] sterilization process is similar to the predicate sterilization processes listed above. Both of these predicate sterilization processes are intended to terminally sterilize orthopaedic implants/medical devices to a Sterility Assurance Level (SAL) of 10^{-6} . When compared to the VHP[®] process, the predicate processes also have similar technological characteristics.

Performance Characteristics

The Orthopaedic Division of Smith & Nephew, Inc. has conducted numerous tests as supporting evidence that the VHP[®] sterilization process is qualified for sterilization of all UHMWPE orthopaedic implants in the Cofield², Neer II, and Neer III Total Shoulder Systems by demonstrating the following:

- Microbicidal effectiveness of the vaporized hydrogen peroxide
- The effects of the VHP[®] sterilization cycle on UHMWPE material and the materials in which the product is packaged
- Process validation efforts to demonstrate that the VHP[®] sterilization process is effective and reproducible resulting in a SAL of at least 10^{-6}

Test results demonstrated that the VHP[®] sterilization process is capable of terminally sterilizing UHMWPE orthopaedic implants and verifies achievement of a SAL of 10^{-6} . The VHP[®] sterilization process was also demonstrated to be safe, reproducible, predictable and effective in sterilizing UHMWPE orthopaedic implants packaged and sealed in Tyvek[®]/Mylar[®] pouches.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2002

Mr. David Henley
Senior Clinical/Regulatory Affairs Specialist
Orthopedic Division
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K012788

Trade/Device Name: UHMWPE Components of the Cofield², the Neer II, and the Neer III
Total Shoulder Systems

Regulation Number: 21 CFR 888.3660

Regulation Name: Shoulder Joint Metal/Polymer, Semi-constrained Cemented Prosthesis

Regulatory Class: Class II

Product Code: KWS

Dated: December 14, 2001

Received: December 17, 2001

Dear Mr. Henley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

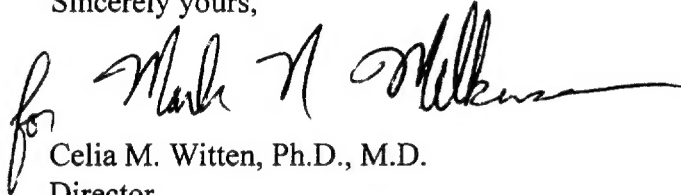
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. David Henley

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Premarket Notification
Indications Enclosure**

510(k) Number (if known): K012788

Device Name: UHMWPE Components of the Cofield², Neer II, and Neer III Total Shoulder Systems Sterilized with the VHP[®] Sterilization Process

Indications for Use:

The Cofield² Total Shoulder System, the Neer II Total Shoulder System, and the Neer III Total Shoulder System are indicated for use as orthopaedic implants for the partial or total replacement of the human shoulder joint articulating either directly against the glenoid face or a compatible glenoid component, respectively.

The Cofield² Total Shoulder System, the Neer II Total Shoulder System, and the Neer III Total Shoulder System are intended for the following:

Proximal Humeral Prosthesis – (1) complex, acute fractures or fracture-dislocations of the humeral head (e.g. trauma - three and four-part injuries in the Neer classification, or head splitting, or head impression fractures); (2) complex, chronic fractures or fracture-dislocations of the humeral head with malunion, nonunion of a small osteoporotic head fragment, or chronic dislocation with loss of humeral head cartilage, or large impression fractures; (3) avascular necrosis with intact glenoid cartilage; and (4) selected patients with arthritis who do not have adequate scapular bone to support a glenoid component or must engage in moderately heavy activities.

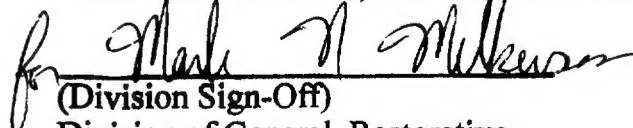
Total Shoulder Arthroplasty (when used in conjunction with a compatible glenoid component) – severe destruction of the glenohumeral articular surfaces with intractable chronic pain in rheumatoid arthritis, osteoarthritis, traumatic arthritis, cuff tear arthroplasty, ancient septic arthritis avascular necrosis with secondary glenoid changes, radiation necrosis, and other failed reconstructive procedures. The subject all poly glenoid components are intended for cemented fixation only and for single use only.

The Orthopaedic Division of Smith & Nephew, Inc. will utilize the VHP[®] sterilization process to terminally sterilize all polyethylene glenoid components manufactured from UHMWPE material in the following product systems:

- *Cofield² Total Shoulder System* (all polyethylene glenoid components)
- *Neer II Total Shoulder System* (all polyethylene glenoid components)
- *Neer III Total Shoulder System* (all polyethylene glenoid components)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K012788

Prescription Use 32
CFR 801.109)

OR

Over-the-Counter Use N. (Per 21
(Optional Format 1-2-96)